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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Blood and Tissue Safety and Availability

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S.

Department of Health and Human Services is hereby giving notice that the Advisory

Committee on Blood and Tissue Safety and Availability (ACBTSA) will hold a meeting.

The meeting will be open to the public.

DATES: The meeting will take place Wednesday, December 4 from 8:00 a.m. to 5:00 p.m. and Thursday, December 5, 2013 from 8:00 a.m. to 4:00 p.m.

ADDRESSES: NIH Conference Room, 5635 Fishers Lane, Rockville, MD 20892.

FOR FURTHER INFORMATION CONTACT: Mr. James Berger, Senior Advisor for Blood and Tissue Safety Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, 1101 Wootton Parkway, Suite 250, Rockville, MD 20852; phone: (240) 453-8803; fax: (240) 453-8456; e-mail: ACBTSA@hhs.gov.

SUPPLEMENTARY INFORMATION: The ACBTSA shall provide advice to the Secretary through the Assistant Secretary for Health. The Committee advises on a range of policy issues to include: (1) Definition of public health parameters around safety and availability of blood and blood products as well as tissues and tissue products, (2) broad public health, ethical, and legal issues related to transfusion and transplantation safety, and (3) the implications for safety and availability of various economic factors affecting product cost and supply. The advisory committee has met regularly since its establishment in 1997.

At the December 2013 meeting the ACBTSA will hear updates on recent activities of the Department and its agencies in support of previous Committee recommendations. Past recommendations made by the ACBTSA may be viewed at www.hhs.gov/bloodsafety.

This meeting will serve as a continuation of the June 2013 ACBTSA meeting, which addressed whether the current construct of the blood collection center system in the United States is designed for optimal service delivery in the era of health care reform. In particular, this meeting seeks to evaluate the cost recovery system of blood centers, their perceived capacity for product and services innovations, and to promote risk based decision making from donor to recipient. The Committee will also hear from the World Health Organization's NOTIFY Library Project and their efforts to improve vigilance and surveillance of adverse transplant events relating to human cells, tissues, and organs. Additionally, the Committee will receive updates on recommendations from the ACBTSA Subcommittees addressing Disaster Preparedness; Tissue and Blood Safety; and Informed Consent in Transfusion and Transplantation.

The public will have the opportunity to present their views to the Committee during a

public comment session scheduled for December 4, 2013. Comments will be limited to

five minutes per speaker and must be pertinent to blood and tissue safety and availability.

Pre-registration is required for participation in the public comment session. Any member

of the public who would like to participate in this session should to contact the designated

Federal official to register prior to close of business on December 2, 2013. If it is not

possible to provide 30 copies of the material to be distributed, then individuals are

requested to provide a minimum of one (1) copy of the document(s) to be distributed

prior to the close of business on December 2, 2013. It is also requested that any member

of the public who wishes to provide comments to the Committee utilizing electronic data

projection to submit the necessary material to the Executive Secretary prior to the close

of business on December 2, 2013.

Dated: October 28, 2013.

James J. Berger,

Senior Advisor for Blood and Tissue Safety Policy.

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